

What is claimed is:

ART 34 A44

1. A gel mass composition comprising
 - a) a film-forming, water-soluble polymer,
 - b) an acid-insoluble polymer; and
 - c) an aqueous solvent; and, optionally,
 - d) at least one plasticizer; and, optionally,
 - e) a coloring agent.
2. The gel mass composition of claim 1, wherein the film-forming, water-soluble polymer is proteinaeous.
3. The gel mass composition of claim 2, wherein the proteinaeous film-forming, water-soluble polymer is gelatin.
4. The gel mass composition of claim 3, wherein the gelatin is extracted from animal bones or skins, and has about 100 to about 250 blooms.
5. The gel mass composition of claim 1, wherein the film-forming, water-soluble polymer is a carbohydrate.
6. The gel mass composition of claim 5, wherein the carbohydrate is selected from the group consisting of hydroxypropyl methylcellulose and methyl cellulose.
7. The gel mass composition of claim 1, wherein the film-forming, water-soluble polymer is selected from the group consisting of acrylic and methacrylic acid copolymers, cellulose acetate esters such as phthalate, butyrate, hydroxypropyl methyl cellulose phthalate, and salts thereof.
8. The gel mass composition of claim 1, further comprising at least one plasticizer selected from the group consisting of sorbitol, glycerol, polyethylene glycol, polyalcohols with 3 to 6 carbon atoms, citric acid, citric acid esters, triethyl citrate, and

combinations thereof.

9. The gel mass composition of claim 1, wherein the aqueous solvent is water.
10. The gel mass composition of claim 1, wherein the aqueous solvent is an alkaline aqueous solution.
11. The gel mass composition of claim 1, wherein the alkaline aqueous solution comprises an alkali selected from the group consisting of ammonia, sodium hydroxide, potassium hydroxide, ethylenediamine, hydroxylamine, and tri-ethanolamine.
12. The gel mass composition of claim 1, wherein the alkaline aqueous solution comprises a volatile alkali.
13. The gel mass composition of claim 12, wherein the volatile alkali is selected from the group consisting of ammonia and ethylenediamine.
14. The gel mass composition of claim 11, wherein the aqueous solution is a hydroalcoholic solution.
15. The gel mass composition of claim 10, where the final pH of the gel mass is less than or equal to about 9.0 pH units.
16. The gel mass composition of claim 10, where the final pH of the gel mass is less than or equal to about 8.5.
17. A gel mass composition comprising
 - a) a film-forming, water-soluble polymer,
 - b) an acid-insoluble polymer; and
 - c) an aqueous solvent;wherein the moisture content of the gel mass composition is from about 2% to

about 10%.

18. The gel mass composition of claim 20, wherein the moisture content is from about 4% to about 8%.
19. The gel mass composition of claim 20, wherein the moisture content is about 8%.
20. A gel mass composition comprising
 - a) a film-forming, water-soluble polymer,
 - b) an acid-insoluble polymer; and
 - c) an aqueous solvent;wherein the ratio of acid-insoluble polymer to film-former polymer is from about 20:80 to about 45:55 by weight.
21. A gel mass composition comprising
 - a) a film-forming, water-soluble polymer,
 - b) an acid-insoluble polymer;
 - c) an aqueous solvent; and
 - d) a plasticizer,wherein the ratio of plasticizer to film-forming, water-soluble polymer is from about 1:9 to about 1:1 by weight.
22. The gel mass composition of claim 24, wherein the ratio of plasticizer to film-forming, water-soluble polymer is about 1:3 by weight.
23. An enteric soft capsule shell composition, comprising
 - a) a film-forming, water-soluble polymer,
 - b) an acid-insoluble polymer; and
 - c) an aqueous solvent;wherein the moisture content of the gel mass composition is from about 2% to about 10%, and the ratio of acid-insoluble polymer to film-former polymer is from

about 20:80 to about 45:55 by weight.

24. A process of manufacturing a shell composition into soft capsules, the process comprising
 - a) preparing a solution comprising a film-forming, water-soluble polymer and an acid-insoluble polymer and mixing with appropriate plasticizers to form a gel mass;
 - b) casting the gel mass into films or ribbons using heat-controlled drums or surfaces; and
 - c) forming a soft capsule using rotary die technology.
25. The process of claim 17, wherein the thickness of the films or ribbons is from about 0.015 inches to about 0.050 inches.
26. The process of claim 17, wherein the thickness of the films or ribbons is about 0.020 inches.